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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,347	10/17/2003	John Gregory Slatter	01411.US1	2299
25533	7590	01/12/2005	EXAMINER	
PHARMACIA & UPJOHN 301 HENRIETTA ST 0228-32-LAW KALAMAZOO, MI 49007			OH, TAYLOR V	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/688,347	<b>Applicant(s)</b> SLATTER, JOHN GREGORY	
	<b>Examiner</b> Taylor Victor Oh	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Final Rejection

**The Status of Claims**

Claims 1-11 are pending.

Claims 1-10 have been rejected.

Claim 11 is allowable.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claim 11 under 35 U.S.C. 112, first paragraph, has been withdrawn due to applicants' convincing argument in the amendment.

**Claim Rejections - 35 USC § 102**

1. Applicants' argument filed 10/12/04 have been fully considered but are not persuasive.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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**The rejection of Claims 1-2 ,7 and 9-10 under 35 U.S.C. 102(b) as being anticipated clearly by Guittard et al (U.S. 5,840,754) disclosed in the STN search has been maintained .**

The rejection of Claims 1-2 ,7 and 9-10 under 35 U.S.C. 102(b) as being anticipated clearly by Guittard et al (U.S. 5,840,754) disclosed in the STN search has been maintained for the reasons of the record on 7/13/04.

**Claim Rejections - 35 USC 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**The rejection of Claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Guittard et al (U.S. 5,840,754) disclosed in the STN search has been maintained for the reasons of the record on 7/13/04.**

The rejection of Claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Guittard et al (U.S. 5,840,754) disclosed in the STN search has been maintained for the reasons of the record on 7/13/04.

**Applicants' Argument**

Applicants argue the following issues:

- a. Guittard (5,840,754) does not disclose the claimed compound 1, but has revealed only oxybutynin, oxybutynin hydrochloride salt and desethyloxybutynin; therefore, Claims 1-2, and 9 and 10 are not anticipated by Guittard based on the STN search;
- b. There is no teaching or suggestion in Guittard that oxybutynin would have any activity if the nitrogen atom would be tied up completely by a fourth covalent bond;
- c. The mere mentioning of the hydrochloric acid salt of oxybutynin does not suggest or motivate the skilled artisan in the art to change from a hydrochloric acid salt of a tertiary amine to the quaternary ammonium salt thereof since the fourth covalent bond to nitrogen has a significant effect on the chemical and biological properties of the compound and the similar reason can be applied to desethyloxybutynin.

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the first argument, the Examiner has noted applicants' arguments. However, the STN has the claimed 4-[(cyclohexylhydroxyphenylacetyl)oxy]-N,N-diethyl-N-methyl-2-butyne-1-aminium, nitrate compound with its registry number (350229-43-5); its therapeutic use can be in the management of overactive bladder in the summary of the STN search. This means that the STN is the prior art for the claimed compound regardless of where it came from. The STN has already revealed that US

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Patent Nos. (6,262,115), (5,674,895), (5,840,754), and (5,912,268) may have contain the claimed compound. Even if it is impossible to find the claimed compound among those patents, nothing will change the fact that the claimed compound has been known in the public domain evidence provided by the STN search with its registry number (350229-43-5). Therefore, applicants' argument is irrelevant to the issues of the currently claimed invention.

Second , regarding the second and third arguments , the Examiner has noted applicants' arguments. However, since the STN has the claimed compound 's registry number which may be found in the prior art, applicants' argument regarding the chemical and biological properties of the oxybutynin and the hydrochloric acid salt of oxybutynin and desethyloxybutynin compared to those of the claimed compound is pointless. Therefore, applicants' argument is irrelevant to the issues of the currently claimed invention.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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11/8/05

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